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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,257	12/14/2001	Jangbir S. Sangha	CHO004/106011	8707

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EXAMINER	
FREDMAN, JEFFREY NORMAN	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 12/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/020,257	SANGHA ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-29,32-36,38,40-55,66,68-76,78-86 and 88-102* is/are pending in the application.

4a) Of the above claim(s) *7-25,40-55 and 96-102* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-29,32-36,38,66,68-76,78-86 and 88-95* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 25, 2004 has been entered.

Claim Rejections - 35 USC § 102

2. The rejection of claims 1, 2, 4, 56, 57, 59 and 62-64 under 35 U.S.C. 102(b) as being anticipated by Covalciuc et al (J. Clin. Microbiol. (1999) 37:3971-3974) is moot in view of the cancellation of these claims.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. The rejection of claims 1-3, 56-58 and 62-64 under 35 U.S.C. 103(a) as being unpatentable over Ricciardi et al (U.S. Patent 6,291,171) in view of Deragon et al (Nucleic Acids Research (1990) 18(2):6149) is moot in view of the cancellation of these claims.

6. The rejection of claims 1-6, 56-64 under 35 U.S.C. 103(a) as being unpatentable over Ricciardi et al (U.S. Patent 6,291,171) in view of Northview Biosciences Inc. (March 2001) (titled Sterility Assurance Compliance) (http://www.northviewlabs.com/pdf_docs/SterilityAssurance.pdf) is moot in view of the cancellation of these claims.

7. Claims 26-29, 32-36, 38, 66, 68-76, 78-86 and 88-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ricciardi et al in view of Furcht et al (U.S. Patent 6,303,288) in view of Northview Biosciences Inc. (March 2001) (titled Sterility Assurance Compliance) (http://www.northviewlabs.com/pdf_docs/SterilityAssurance.pdf).

Ricciardi et al teaches a kit for the collection of material containing DNA (see abstract and figure 1) comprising:

(a) a housing containing at least one collection device for collection material containing DNA (see figure 1 and column 2, lines 30-42).

Ricciardi expressly teaches that the swabs may be used for PCR amplification and that the swabs should be sterile (see column 2, lines 5-10).

With regard to claim 56, Ricciardi teaches a tubular holder, see figure 1, hole 30a, which is tubular shaped and which permits extension and retraction through the holder (see figure 1).

With regard to claims 62-64, Ricciardi teaches the use of Dacron swabs which have some level of adhesion that is variable in it's binding (see column 3, lines 36).

Ricciardi et al does not teach modes of sterilization.

Northview Biosciences teaches sterilization of kits using a variety of equivalent techniques including ethylene oxide, gamma radiation and electron beam radiation (see page 2)

With regard to claims 76 and 86, Ricciardi teaches placement of the swabs in a protective pouch (see figure 1).

With regard to claims 32-35, 39, 68-71, 78-81, 88-91, Northview Biosciences teaches sterilization of kits using a variety of equivalent techniques including ethylene oxide, gamma radiation and electron beam radiation (see page 2)

Ricciardi et al in view of Northview Biosciences Inc. do not teach a device which has a rear surface that prevents collection of the DNA.

Furcht et al teaches, with regard to claims 26, 36, 38, 66, a device for the collection of material containing DNA (see abstract and figure 1) comprising:

A device for collecting material containing DNA that has a collection portion, (figure 3, reference number 32, which column 8, lines 54-67 identifies as a sample

collection pad that is placed on a plastic support, reference number 31 (see column 8, lines 41-44), where the figure shows a front surface that is available for the collection of material containing DNA and a rear surface that is covered by plastic and is not available for DNA collection (see figure 3).

With regard to claims 27-29, Furcht teaches buccal scraping (see column 8, line 62). Further, these limitations do not impose any structural requirements on the product and simply represent intended uses of the product. As MPEP 2111.02 notes "Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art." Here, no such structural difference currently exists.

With regard to claims 65, 72-75, 82-85, 92-95, Furcht teaches the use of FTA paper which inherently has some level of adhesion that is at least slightly variable in it's binding (see column 8, line 58).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the device of Furcht in the kit of Ricciardi since Furcht notes "This application of the microcantilever based sensor offers superior sensitivity, specificity and utility in an integrated MEMS system format (see column 12, lines 7-10)." Furcht further motivates the use of FTA paper by noting "DNA extractions on FTA^{tm} paper have demonstrated significant ease in use and reduced cost in performing routine clinical molecular genetic testing (see column 2, lines 53-56)."

Motivation to sterilize the device is provided by Northview Biosciences which notes "Sterility is essential to the safety of many medical devices. Most single use devices are terminally sterilized by ethylene oxide gas or gamma or electron beam radiation (see page 2)". An ordinary practitioner would have been motivated to use the device of Furcht in the kit of Ricciardi since the device will improve sensitivity, specificity and utility and reduce labor costs and specimen sizes (see column 12 and column 2, lines 21-38). Further, an ordinary pracititioner would have been motivated by Northview biosciences to sterilize the kit in order to improve the safety of the device and to ensure that swabs, which would be placed within the oral cavity of human beings, would not contain any hazardous materials such as pathogenic microorganisms or viruses.

Response to Arguments

8. Applicant's arguments filed November 8, 2004 have been fully considered but they are not persuasive.

Applicant argues that the sample collection pad of Furcht, identified as number 31 in figure 3, is not covered by a plastic strip. While well argued, the argument is totally focused upon the figure. Applicant specifically argues at page 22 of the response that "Close examination of figures 1 and 3 of the Furcht '288 patent shows that plastic support strip 31 terminates adjacent or under cocktail pouch 33 and that only a portion of collection pad 32 is mounted onto cocktail pouch 33 and none of pad 32 is attached to strip 31. In fact in Fig. 3 strip 31 appears to terminate at or under pouch 33."

This argument cannot be correct because it fails to appreciate the teachings of the specification of Furcht. The specification of Furcht states "The gene strip 11 is

comprised of a flexible plastic support 31 onto which is affixed the sample collection pad 32 and the reaction cocktail pouch 33 with attached cocktail fluid tube 35, depicted in phantom in figure 3 underlying a portion of the collection pad 32 and fluidly coupling the cokctail pouch 33 and the collection pad 32 (see column 8, lines 41-48)."

So Applicant's interpretation that "none of pad 32 is attached to strip 31" is directly contradicted by the Furcht patent's statement that "The gene strip 11 is comprised of a flexible plastic support 31 onto which is affixed the sample collection pad 32 (see column 8, lines 41-43)." Applicant's argument must therefore fail because Applicant is incorrectly viewing Furcht's figure. Strip 31 of Furcht must underlie the entire device, end to end, or else the statement by Furcht in the specification that pad 32 is attached to strip 31 is not given weight. Since the patent's own disclosure controls the meaning of the invention, Furcht's express statement that strip 31 is attached to pad 32 must be given weight and strip 31 must underlie pad 32.

That Furcht intends for strip 31 to underlie pad 32 can be seen by analogy to mark 34. Furcht indicates that "Additionally, the genestrip 11 contains a space at the opposed end thereof dedicated to the placement of test/sample/patient identifier mark 34, which is embodied as a bar code, magnetically encoded data strip or other addressable marking system (see column 9, lines 20-24)." If Applicant's reading of figure 3 is correct, then strip 31 would also terminate at element 34. However, column 8, lines 42-43 makes clear that "The genestrip 11 is comprised of a flexible plastic support 31". So how can genestrip 11, which is made up of flexible plastic support 31, have a space for mark 34 as required by column 9, lines 20-24, unless strip 31

underlies mark 34. This shows that the specification description indicates that all of the elements are placed onto a basal support which is strip 31.

Applicant's argument is therefore not persuasive because the express statement of Furcht that "The gene strip 11 is comprised of a flexible plastic support 31 onto which is affixed the sample collection pad 32 (see column 8, lines 41-43)" demonstrates that support 31 is placed underneath pad 32, providing a plastic covering which prevents the rear surface from collecting DNA. This meets the requirements of claims 26, 36, 38, 66, 76 and 86.

Conclusion

9. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey Fredman
Primary Examiner
Art Unit 1637
12/3/04